SUPREME COURT, U. S.

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IN THE

Supreme Court of the United States

October Term, 1962

No. 643

NATURE FOOD CENTRES, INC., and HENRY K. ROSENBERGER and ANDREW G. ROSENBERGER,

Petitioners,

AGAINST

UNITED STATES OF AMERICA,

Respondent.

PETITIONERS' REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

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The petition, heretofore filed, clearly sets forth the questions presented which warrant review. The Government has failed to respond to these questions and has instead created an irrelevant premise for the purpose of extensive argument.

The Government's brief (on page 2 thereof) attempts to combine three statements into one purported question presented. This question, however, is not the question presented for review. Thus, the Government states in its question presented that the notes did not mention the drugs by name in the class notes. The issue in this case

is not whether the drugs are mentioned by trade name in the labeling material. The issue presented in this case is whether the disease conditions, and not the drug names, are mentioned by name in the labeling material. It is further submitted that separate and apart from its non-applicability in this case, it is also irrelevant under the Federal Food, Drug and Cosmetic Act. Literature has been held to constitute labeling for a product, under the Act, which makes no mention whatsoever of the product by trade name, but rather by its ingredients or components. See *United States* v. *8 Cartons, etc.*, 97 F. Supp. 313 and 103 F. Supp. 626 (W. D. N. Y., 1951) where a book was held to constitute labeling for a product wherein the product is nowhere mentioned by its trade name, but solely by a reference to the ingredient. This has similarly been true in other cases involving literature and books, including *V. E. Irons, Inc.* v. *United States*, 244 F. 2d 34 (C. C. A. 1, 1957), and cases involving Dr. Jarvis' book titled "Folk Medicine".

It may be noted that there is a more precise designation of the product in the instant case than that which was present in other cases herein cited such as the *Irons* case, *supra*, wherein various newsletters merely discussed nutrition and vitamins in general terms whereas in the instant case, the products are specifically identified by the principal ingredient such as Vitamin B or Vitamin C, in the labeling notes. The Government has set forth and created this nonexistent issue and thereupon proceeds to argue its self-created question on pages 6 and 7 of its brief.

The same omnibus question presented also incorporates another irrelevant statement wherein it states, at the end of the paragraph, that the notes frequently did not accompany the drugs at the time they were sold. This ques-

tion is similarly not the issue presented herein. The literature does not have to be with the product at the time that it is sold to constitute labeling for the product. That is precisely what this Court said in *Kordel* v. *United States*, 335 U. S. 345 (1948), *United States* v. *Urbuteit*, 335 U. S. 355 (1948), and *United States* v. *Urbuteit*, 336 U. S. 804 (1949). In the *Kordel* case, *supra*, the argument was made that the literature must be with the product as to time and physical proximity to satisfy the statutory requirement of "accompanying". This Court did not accept this requirement and ruled that the statutory "accompanying" between the product and the literature could even be eighteen months apart so long as the literature was used as part of an interdependent distribution program in the marketing of the product.

The Government's brief contains extended argument premised upon these questions which are neither material nor relevant to the review sought by the petitioners. Thus, on pages 5 and 7 of the Government's brief, we find continued references to this alleged issue of the literature not being at the store. It is further significant that none of the counts in the information involve an alleged misbranding while the products were held for sale at the store, but rather allege misbranding when the products were introduced into and while in interstate commerce.

On page 7 of its brief, the Government states, in the first sentence under its heading of "Argument", that petitioners concede that the labeling on the drugs do not constitute adequate directions for use. No such concession was made. The Government has incorrectly used the term *labeling* as distinguished from the term *label*. As discussed in the petition herein, this distinction is a significant factor in this case, as Congress has clearly and spe-

cifically distinguished the term *labeling* from the term *label*, both as to definition and requirements under the Act.

The Government further argues, on the bottom of page 7 of its brief, that the issue of whether the class notes constitute labeling under the Statute is essentially a factual question. This is not true. The definition of labeling and more specifically the interpretation of the word *accompanying* in the statutory definition, is a question of law. This Court most certainly considered it to be a question of law in its rulings in the *Kordel* and *Urbuteit* cases, *supra*. In the instant case, the Court of Appeals failed to apply the definition of labeling laid down by this Court, and instead created two different definitions for this same statutory term varying with the section of the Statute in which it appears.

On page 10 of its brief, the Government first attempts to argue that the term "labeling" has not been given different meanings. The Government states that documents which accompany some articles may be false as to those articles even though they are obviously not false as to other articles which they do not accompany. The Government uses the word *accompany* in its literal sense, as a physical concept, rather than as a statutory word of art. Furthermore, this statement is inconsistent with the law laid down by this Court in *Kordel*, *supra*, where this Court held that there is no need for a physical accompanying or presence at the same point of sale so long as they are part of the same integrated distribution program.

It is respectfully submitted that if the Government's argument is correct, then the Government's case must fall by applying its own desired rule of law. The stipulated evidence in this case demonstrates that the claims for the product were not made at the stores, but only at the

lecture halls. The only possible manner by which the Government can establish the first prerequisite for its case, is to apply the claims made in the lectures, at the lecture hall, to the shipment initiated in Massachusetts, which went to both the store and the lecture hall. The only theory whereby said lectures can be applied back to the products at the time of shipment, would be that the lectures were part of the integrated distribution program. To the very same extent that the lectures were part of the integrated distribution program, so too, were the class notes, which were displayed, distributed and available for distribution at those very same lectures together with the products at the lecture hall. The class notes were, therefore, as much a part of the integrated distribution program as the lectures and co-extensive therewith. If the Government contends that we must draw a sharp line of separation between the products shipped from Massachusetts which went to the store and the products which went to the lecture hall, then the same separation must be made for the claims which were made for the products in the lecture hall and which were not made at the store. The Government's contention is self-contradictory and contrary to the decisions of this Court. It is, furthermore, immaterial that an individual received the class notes at the lecture hall and then bought the product at the store. There is no requirement that the product and the literature be together at the same place either physically or in point of time, *Kordel* v. *United States*, *supra*.

On pages 10 and 11 of its brief, the Government attempts to discuss the legal definition of the term labeling applicable herein. It discusses various criteria which it claims are required in order for literature to constitute labeling under the Act. These criteria are contrary to and inconsistent with the definition of the term labeling

heretofore laid down by this Court in *Kordel* and *Urbuteit*, *supra*.

Thus, on page 11 of its brief, it argues that the documents must not be "far removed from the point of sale", and again it states that the labeling material must be "closely enough associated with the drug at the point of its sale". These requirements are precisely the kind of requirements which have been held to be unnecessary in order for literature to accompany a product so as to constitute labeling under the Statute, *Kordel* and *Urbuteit*, *supra*.

The Government further injects on pages 10 and 11 of its discussion of the legal issue herein, the additional word adequate in front of the word labeling. The term in the Statute is not *adequate labeling*, but rather the term *labeling*.

Literature either is labeling under the law or it is not labeling. The legal determination relative thereto has nothing whatsoever to do with any question of adequacy. The issue is whether the literature is labeling, and if so, whether it contains the names of the diseases charged in the information to be missing therefrom. These are two separate questions as discussed in the petition.

The Government comments in the last paragraph on page 11 of its brief, that the requirements can be readily met by "honest enterprise" * by including the promotional material at the point of sale. The question herein is not whether certain requirements can be met. The question is rather as to the requirements which are in fact set forth in the Food, Drug and Cosmetic Act, and the rulings of

* There is no question herein as to so called honest enterprise. There is no charge in the information that any false or misleading claims have been made for the products.

this Court as to such requirements. This Court has heretofore clearly ruled that literature constitutes labeling for a product even though it is not present at the point of sale or physically proximate to the product. If the Government desires to change the requirements of the Act, then such changes should be made by legislative action.

Respectfully submitted,

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January 1963.